Interviews

EMJ had the privilege of speaking to three leading figures in diabetes research: Dame Melanie Davies, Michael Roden, and David M. Nathan. Davies explores advances in diabetes prevention, personalised care, and the translation of research into clinical practice; Roden discusses the metabolic complexity of diabetes, including insulin resistance, mitochondrial function, and precision diabetology; and Nathan reflects on landmark clinical trials, the evolution of diabetes treatment, and the future of personalised therapies and long-term disease prevention.

Featuring: Dame Melanie Davies, Michael Roden, and David M. Nathan



Dame Melanie Davies

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Interviewer:	Bertie Pearcey, EMJ, London, UK
Citation:	EMJ Diabet. 2026;14[1]:61-66. https://doi.org/10.33590/emjdiabet/T52183AF

Q1 Since your key role in the establishment of the Leicester Diabetes Centre in 2009, a lot of your work has focused on finding ways to intervene earlier in the course of Type 2 diabetes (T2D). What have you learned about the people who are most likely to benefit from earlier intervention, and what can be done to reach them sooner?

A lot of our early work was around screening. I'm fortunate enough to work in Leicester, UK, which is a very diverse city, particularly with people from the South Asian population, who tend to develop T2D at a younger age and lower BMI, and often have a much stronger family history. So, I think people of South Asian ethnicity are one population to focus on, but then there are clearly many other areas that put people at higher risk of developing T2D.

An example of our work was the Cities Changing Diabetes campaign, which was born out of a few questions such as: how could people be screened early? What are the early symptoms of T2D? What can we do in schools, workplaces, and sports clubs?

In Leicester, we ran a campaign called Leicester United, where we had the football, rugby, cricket, and basketball teams working together to promote some less intensive interventions, such as active walking and walking cricket. This attracted people who go to watch sports but don't participate, and allowed us to use facilities across the city to help people access interventions that can prevent the onset of T2D.

We now understand a lot more about the modifiable risk factors. We know that weight plays a big role. We know that the 24-hour

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physical behaviours, like sedentary behaviour and physical activity, play a role. We know that different ethnicities, such as South Asian and Afro-Caribbean populations, have a higher risk of T2D. We're also seeing T2D present at a much younger age. We know that identifying people with early onset T2D is really important.

Q2 Diabetes diagnoses in young people in the UK are at an all-time high, particularly with younger women. How can policymakers and HCPs better approach this at-risk group to improve health outcomes? What needs to change in how we approach people in these groups, clinicians, and policymakers if we are to reverse this trend?

We've seen a huge increase in the number of people presenting with T2D under the age of 40 years, even under the age of 25 years. In Leicester, our youngest patient was only 8 years old. When I started in the clinic 10–20 years ago, we had virtually nobody with T2D under 50 years. Now, I have a specialist clinic where I see people living with T2D under the age of 40 years, many of those being in their late teens and early 20s.

This is important, because many of the interventions, whether that's self-management, physical activity, or medicines, have been tested and developed for people in their 40s–60s, and virtually no people under that age have been included in those trials or evidence base.

The second thing is that the pathophysiology seems to be different. Younger people see more accelerated progression of their T2D and they're more prone to some of the complications, particularly things like renal disease. We know that people increasingly live with multiple long-term conditions associated with diabetes, but this is particularly an issue in young people, because, in addition to the physiological burden, they may also have mental health problems, such as depression.

As we're often dealing with a working age population or people who have dependents, the way we design the models of care needs to be appropriate for that age group as well. What we're testing at the moment in Leicester is a programme grant looking at a complex intervention called M3. It is a very person-centred, holistic approach designed by people living with early onset T2D to minimise the burden of care. This includes the medicines, technology, 24-hour physical behaviours, psychological support (which is often lacking), and self-management support.

Q3 The Leicester Diabetes Risk Score, which your team developed, has moved from a research tool into something that is usable at population scale. What have you learned from seeing research tools implemented in real-world health settings?

Kamlesh Khunti, University of Leicester, UK, and I decided early on that we wanted to do things differently. There didn't seem to be many groups that worked across the hospital in primary care, and into the university. One of the things that defined our programmes was the voices of the people that we were seeing in primary care or our clinics.

There was lots of work done in Finland and in Cambridge, UK, around risk scores, but they were focused on a White population, which didn't reflect the diversity of the broader population. Initially, at the Lord Mayor's appeal in Leicester, we were able to fund a screening bus, where we collected hundreds of new glucose tolerance tests, HbA1cs, and patient information that we were able to use to validate and develop a risk score that was suitable for the UK, so, very early on, we linked with Diabetes UK, who took the risk score and put it on their website. More than three million people have used that risk tool now, which we, through work led primarily by Laura Gray, University of Leicester, UK, continue to improve.

In general, our research is guided by some key principles:

- It works across organisations: the NHS, academia, communities, hospitals, and primary care.
- It's driven by the clinical need of the people that we see in our clinics and experience.
- It needs to translate to impact.

We see lots of great academic institutes and research, but the difference that research makes for actual people can be limited.

Q4 You have also led some of the most influential work on diabetes self-management and education, with programmes such as Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) also being adopted at scale. With so many new drugs and technologies now available, do you think we risk underestimating the continuing importance of helping people living with diabetes develop the skills and confidence to manage their diabetes themselves?

> **We see lots of great academic institutes and research, but the difference that research makes for actual people can be limited**



DESMOND started when the National Institute for Health and Care Excellence (NICE) review came out around structured self-management. The gap that was identified was that there were no evidence-based self-management programmes. As a result, Kamlesh and I worked with Diabetes UK (who funded the first study), setting out to do a trial to prove the self-management programme worked. We felt that it was important to offer people high-quality self-management, but we had to show it was efficacious and cost-effective to ensure funding going forwards.

At the time, it was the world's largest trial of self-management education across the whole of the UK in primary care. After we published the initial paper and cost-effectiveness analysis, DESMOND was commissioned as a national programme.

Recently, we were delighted to be awarded the national tender for digital self-management, underpinned by DESMOND. That has only just been announced, and will be rolling out, which is great.

To summarise, you can have the best medicines in the world, but if you don't have a person at the centre who has been supported by quality self-management

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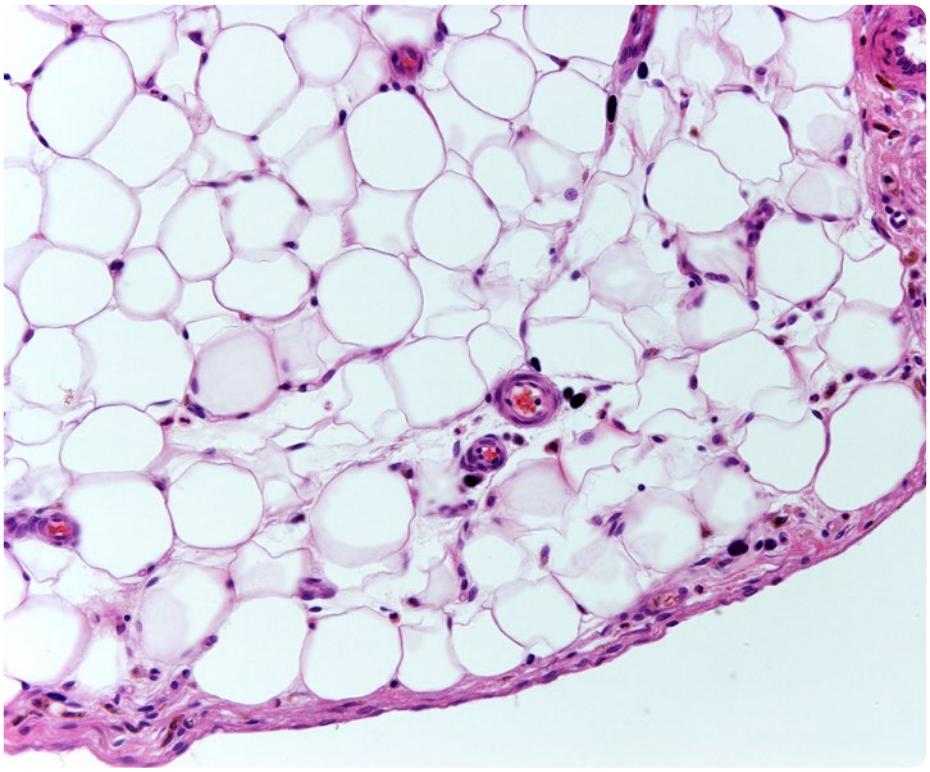
education, then you don't see the benefits of the medicine. People must have the knowledge, skills, and support to make the best of the medicines that are available. So, it's not an either-or; they complement each other.

Q5 The therapeutic landscape for T2D has changed enormously, particularly with glucagon-like peptide 1 (GLP-1)-based treatments and newer approaches to obesity and cardiometabolic disease. From the perspective of someone who has been involved in both the research and translation of these therapies, what do you think clinicians should be most excited about, and are there claims or developments you think are running ahead of evidence which warrant caution?

We talked about obesity and excess adiposity as a key driver of the increase that we're seeing in T2D, especially when we think about how our understanding of obesity has changed from being a passive bystander to an active contributor to around 200 conditions. The UK has some of the highest obesity rates in Europe, so this is a very prominent issue.

For decades, we had medicines that lowered glucose but didn't offer cardiometabolic protection. They were associated with weight gain, often caused hypoglycaemia, and were not particularly effective in lowering HbA1c all the time.

The sodium-glucose cotransporter 2 (SGLT2) inhibitors have changed the game. We've got a tablet which is now off-patent, so is very cheap and accessible. It changes the trajectory of people's chronic kidney disease, modestly lowers weight, and offers protection in terms of heart failure and major adverse cardiovascular events. These are becoming foundational treatments for many people with T2D.



GLP-1 receptor agonists have been around for nearly 15 years in the diabetes field. We now have studies in people living with obesity without diabetes with benefits on reducing major adverse cardiovascular events, and now nearly 15 years of safety with these medicines. With the right clinical supervision in the right group of patients, they are lifesaving and transformative. The bit that colours people's perception is the huge private market, where these medicines are used in, almost, an unregulated way.

We're also currently doing trials with at least 10 or 20 new agents. However, the availability of these medicines is likely to vary, depending on whether they're oral medicines that are much cheaper and easier to take, or whether they're complex dual or triple agonists which target things like the liver or muscle, or have other health benefits. We're just at the start of that journey, which is exciting.

Q6 A recurring theme in your work seems to be the gap between discovering that something works and ensuring that people benefit from it. After more than 1,000 publications and a huge portfolio of translational research, what do you think are still the biggest barriers between evidence and everyday diabetes care in the UK and across Europe, and which of those barriers can we overcome in the short and long term?

I think there's always been this disconnect between the research pathway and implementation. There are a number of reasons for that. Sometimes the research isn't necessarily designed for implementation, and sometimes the results don't show that something is effective or that it will be cost-effective within healthcare systems.

In my team, we've tried hard to make sure that when we're designing even early phase studies, we're thinking about that pathway to implementation. If I think about the M3 programme, we don't know how effective it will be, but we spoke to more than 200 people with early onset T2D, in addition to thinking about the systems that we would use if this worked, to help implementation within the NHS. You can make it more likely that your research can be implemented by making sure that it's designed well.

With medicines, the issue revolves around what's affordable now, as many funding decisions are based on short-term acquisition costs, not on long-term benefits. So, we need to find better approaches that might be more expensive in the short term, but could present some savings overall. Also, there does ideally need to be some rationing and targeting of these treatments to make sure we get the most effective treatments to the people who are likely to get the greatest and most rapid benefit.

In some ways, NICE is an example for how that can be done, but we still have gaps in terms of how quickly we can get those technologies out at scale.

“In my team, we've tried hard to make sure that when we're designing even early phase studies, we're thinking about that pathway to implementation”

Q7 Your research has also had a considerable international dimension, with approaches developed in Leicester being implemented across very different healthcare systems and populations. What have those experiences taught you about which aspects of diabetes care can be transferred between national health systems, and which need to be designed around the communities being served?

I have learned lots about this, particularly over the last 5–10 years. We've led quite a number of the Phase II/III trials of GLP-1s, which linked us with international colleagues, and I've been privileged to be involved with the American Diabetes Association (ADA)-European Association for the Study of Diabetes (EASD) consensus report, which has become something of a global consensus now, because, although it's with Europe and America, a lot of other countries across the world look to it.



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I think there are a number of things that are similar across different parts of the world in terms of the research questions asked, notably around multiple long-term conditions and psychological support that people need. Some key similarities are that people want to be informed about their condition, and they want to receive peer support.

For example, we recently had a clinical fellow from Ghana who, having spent a couple of years at the Leicester Diabetes Centre, has now gone back and is leading the pregnancy and diabetes service for her hospital. Because we link research with patient self-management support, and also with healthcare professional education, we have created an expert alumni network. We're also at a point where we publish a couple of papers every week, which showcases the impact of our work globally as well.



So, while there are differences and you do need to take those into account, many factors are similar. This has made some of our work very translatable.

Q8 You have described 'constant curiosity' as something that continues to drive both you and your team. Looking at the diabetes field now, particularly the rapid development of metabolic therapies, earlier diagnosis, prevention, and personalised care, what are the unanswered questions that most excite you, and what would you like your team to have changed about diabetes care 5–10 years from now?

There are so many questions to answer, and just as you think you've answered one, it tends to bring up another four or five. The bit that concerns me, but is also an opportunity, is when we think about early onset T2D and the concept of accelerated ageing. We published a review looking at the physical function of people with early onset T2D, and their physical function is comparable to that of a population many decades older without diabetes.

We have a world-class team that looks at things like physical activity, breaking sedentary time, resistance exercise, sleep, chronotype, and social jet lag. We have to consider things like when to do physical activity, and if people of South Asian ethnicity need to do more to get the same benefit. Physical activity is such a powerful therapeutic tool, and yet it hasn't been personalised or tested in combination with medicines. We have medicines that can, for example, drive phenomenal reductions in body weight, but we don't know what their impact is on muscle.

There's a whole series of questions around combination therapies and behavioural support to maximise those effects. Furthermore, AI technology and precision medicine have developed hugely in the cancer field, and I think there's still a way to go to learn how we apply that to the cardiometabolic field. Answering these questions will keep us very busy for a long time.